

APPENDIX N

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11 UNITED STATES DISTRICT COURT

12 NORTHERN DISTRICT OF CALIFORNIA

13 SAN FRANCISCO DIVISION

WDB

14 GENENTECH, INC.,

15 Plaintiff,

16 v.

17 THE TRUSTEES OF COLUMBIA
18 UNIVERSITY IN THE CITY OF NEW
19 YORK,

20 Defendant.

CASE NO. 04 1910

COMPLAINT FOR
DECLARATORY JUDGMENT OF
INVALIDITY AND
UNENFORCEABILITY OF U.S.
PATENT NO. 6,455,275 AND
BREACH OF CONTRACT

21 COMPLAINT

50656/63828.1

Reissue of U.S. Patent No.
6,455,275 B1
Issued: September 24, 2002
REISSUE filed June 17, 2004
Exhibit 16

CU 03397

OVERVIEW AND NATURE OF THE CASE

1
2 1. Twenty years ago, The Trustees of Columbia University in the City of New York
3 ("Columbia") obtained its first U.S. patent on a certain invention relating to recombinant DNA.
4 In the two decades since then, Columbia has licensed those patent rights to approximately two
5 dozen companies and has received substantial royalties from those companies - over seventy
6 million dollars from Genentech, Inc. ("Genentech") alone. Columbia obtained the full benefits of
7 the patent coverage on its invention. When patent protection on Columbia's invention expired in
8 August 2000, the invention passed into the public domain. Nonetheless, on September 24, 2002,
9 Columbia obtained a new U.S. patent on the invention. Genentech brings this case to stop
10 Columbia's attempt to illegally recapture the invention from the public domain.

11 2. Columbia's first U.S. patent on the invention at issue here issued in 1983. That
12 patent expired on August 16, 2000, after which the invention was dedicated to the public. After
13 procuring that initial patent, Columbia obtained two additional U.S. patents on the invention.
14 Because those two later patents claimed the same invention as the first patent or merely an
15 obvious variant of it, the United States Patent and Trademark Office ("PTO") required Columbia
16 to disclaim the rights in those two patents after the first patent's expiration date. The inventions
17 claimed in each of those patents were also dedicated to the public after August 16, 2000.

18 3. Notwithstanding the above, some *fifteen years* after first filing its initial U.S.
19 patent application on the invention in 1980, Columbia filed yet another U.S. patent application to
20 try to obtain yet another patent on its invention. Columbia's prosecution of that application was
21 dilatory, and multiple PTO examiners reviewed the application. After seven years, *and some*
22 *twenty three years after its initial filing*, Columbia obtained U.S. Patent No. 6,455,275 ("the
23 '275 patent"). But it did so without filing a terminal disclaimer as it had for the last two patents.
24 The '275 patent should not have issued; having issued, it is invalid and unenforceable. Each of
25 its twenty claims attempts to capture the same invention, or an obvious variant of the same
26 invention, that is claimed in one or more of the three prior expired patents.

27 4. In addition, the doctrine of laches renders the '275 patent invalid and
28 unenforceable. The United States Supreme Court has held that a nine-year delay in prosecution

1 renders a patent unenforceable, *Woodbridge v. United States*, 263 U.S. 50 (1923), and that an
 2 eight-year delay in prosecution renders a patent unenforceable, *Webster Electric Co. v. Splindorf*
 3 *Electrical Co.*, 264 U.S. 463 (1924). Relying on these cases, the Federal Circuit has recently
 4 affirmed that "the equitable doctrine of laches may be applied to bar enforcement of patent
 5 claims that issued after an unreasonable and unexplained delay in prosecution" *Symbol*
 6 *Technologies, Inc. v. Lemelson Medical*, 277 F.3d 1361 (Fed. Cir. 2002).

7 5. Columbia unreasonably delayed the prosecution of the '275 patent. In February
 8 1980, Columbia first filed an application that Columbia asserts supports the claims of the '275
 9 patent. But Columbia did not file the application that matured into the '275 patent until June
 10 1995 – some *fifteen years* later. The delays that Columbia introduced into the prosecution of the
 11 '275 patent are unreasonable and unexplained.

12 6. The '275 patent is also unenforceable due to inequitable conduct in obtaining the
 13 patent. In part because the PTO has limited resources with which to review patent applications,
 14 U.S. patent law obligates a patent applicant and those substantively involved in the prosecution
 15 of a patent application to disclose to the PTO all information known to be material to the PTO's
 16 decision whether to grant the application. Columbia, its named inventors, and/or its patent
 17 prosecutors committed inequitable conduct during the prosecution of the '275 patent, because
 18 they withheld material information from a new patent examiner regarding an earlier rejection and
 19 because they failed to disclose material scientific references with an intent to deceive the PTO.

20 7. The invention claimed in the '275 patent is the same as, or merely an obvious
 21 variant of, the invention claimed in the three earlier U.S. patents that Columbia obtained. The
 22 invention claimed in those patents passed into the public domain as of August 16, 2000.
 23 Columbia has already reaped the full benefit the law allows for its invention. Genentech
 24 therefore seeks this Court's declaratory judgment that each of the claims of the '275 patent is
 25 invalid and unenforceable.

26 8. Genentech also seeks a determination that Columbia has materially breached its
 27 License Agreement with Genentech by improperly terminating the agreement for pretextual
 28

1 reasons. Due to all of the circumstances alleged in this complaint Genentech is not paying
2 royalties to Columbia under the '275 patent.

3 THE PARTIES

4 9. Genentech, Inc., is a Delaware corporation with a principal place of business in
5 this judicial district.

6 10. Upon information and belief, the Trustees of Columbia University in the City of
7 New York is a New York corporation with its principal place of business in New York.

8 JURISDICTION

9 11. This is an action for declaratory relief of patent invalidity and unenforceability
10 arising under the patent laws of the United States, including Title 35 of the United States Code.

11 12. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and
12 2201. As set forth in more detail below, an actual controversy exists between Genentech and
13 Columbia regarding the validity and enforceability of the '275 patent because Columbia has
14 represented to Genentech that the '275 patent is valid and enforceable and that Genentech owes
15 royalties to Columbia pursuant to a license to that patent. The '275 patent is not valid or
16 enforceable; hence Genentech disputes that any royalties are owed based on that patent.
17 Moreover, Genentech has stopped paying royalties to Columbia under the '275 patent, thus
18 establishing subject matter jurisdiction and meeting the standard for declaratory relief.

19 13. This Court may exercise supplemental jurisdiction pursuant to 28 U.S.C.
20 § 1367(a) over Genentech's breach of contract claim. That claim is so related to the other claims
21 for relief that they form part of the same case or controversy under Article III of the United States
22 Constitution. Each of the five claims for relief in this complaint is based on the same set of
23 operative facts and allegations.

24 VENUE

25 14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b): Columbia
26 negotiated a patent license (that includes rights to the '275 patent at issue in this lawsuit) with
27 Genentech, which is a resident of this judicial district; Genentech signed the patent license in this
28 judicial district; Columbia has directed substantial communications regarding the license and the

1 '275 patent to Genentech in this judicial district; Columbia has accepted from Genentech.
 2 substantial sums of money originating from this district pursuant to that license; and Columbia
 3 has indicated to Genentech that Genentech owes royalties under that license based on the '275
 4 patent.

5 **ALLEGATIONS COMMON TO ALL CLAIMS**

6 **Columbia obtains a patent for the invention: the '216 patent.**

7 15. More than twenty years ago, Columbia filed the patent application U.S. Serial No.
 8 06/124,513 ("the '513 application"), which issued as U.S. Patent No. 4,399,216 ("the '216
 9 patent") on August 16, 1983, to Columbia as the assignee of named inventors Richard Axel,
 10 Michael H. Wigler, and Saul J. Silverstein. As issued, the '216 patent contained 73 claims. A
 11 true and correct copy of the '216 patent is attached hereto as Exhibit 1.

12 16. Under U.S. law applicable at the time, the '216 patent expired as of August 16,
 13 2000. After August 16, 2000, the invention claimed in the '216 patent passed into the public
 14 domain.

15 **Columbia obtains the '665 patent.**

16 17. After receiving notice that the '216 patent would issue, on August 11, 1983,
 17 Columbia submitted an application ("the '665 application") that matured into U.S. Patent No.
 18 4,634,665 ("the '665 patent"). The PTO rejected certain claims of the '665 application – "under
 19 the judicially created doctrine of obviousness-type double patenting as being unpatentable over
 20 the prior inventions as set forth in [certain claims] of U.S. patent no. 4,399,216." In particular,
 21 the PTO concluded that those claims "are not patentably distinct from each other" when
 22 compared to claims in the '216 patent.

23 18. In response, Columbia did not contest that the '665 patent claimed the same
 24 invention, or merely an obvious variant of the same invention, that was claimed in the '216
 25 patent. Instead Columbia chose to submit a terminal disclaimer of the allowed claims of the '665
 26 patent by which Columbia agreed that the term of the '665 patent would not extend beyond the
 27 August 16, 2000 expiration date of the '216 patent.
 28

1 19. On January 6, 1987, the '665 patent issued to Columbia as assignee of named
2 inventors Richard Axel, Michael H. Wigler, and Saul J. Silverstein. As issued, the '665 patent
3 contained 23 claims. A true and correct copy of the '665 patent is attached hereto as Exhibit 2.

4 20. The '665 patent issued with the notice that "[t]he portion of the term of this patent
5 subsequent to Aug. 16, 2000 [the '216's expiration date] has been disclaimed." Thus, after
6 August 16, 2000, the invention claimed in the '665 patent passed into the public domain.

7 Columbia licenses its invention to Genentech.

8 21. As the '216 and '665 patents reflect, Columbia's "invention... was made in the
9 course of work under grants numbers CA-23767 and CA-76346 from the National Institutes of
10 Health, Department of Health and Human Services."

11 22. While Columbia's '513 application was pending, the Office of the Assistant
12 Secretary for Health of the Department of Health and Human Services, by letter in response to
13 Columbia's petition, denied Columbia's request for "title to the invention" and that "the
14 nonexclusive, irrevocable, royalty-free license for the government apply only to the United
15 States." The Assistant Secretary's letter also noted that "development is necessary to advance the
16 invention to the point of practical application and to meet Food and Drug Administration
17 Approval. Such development shall include... identifying and cloning eucaryotic cells;
18 preparing biologically significant materials using the process of the invention; and preparing,
19 isolating, and characterizing biologically significant materials produced using the process of the
20 invention." The Assistant Secretary imposed conditions on Columbia, including: (1) that the
21 inventors "assign all of their rights in the invention to the University"; (2) that the University
22 shall report to HHS "regarding the development and commercial use that is being made and is
23 intended to be made of the invention"; and (3) that the "University shall use all reasonable efforts
24 to bring the invention to the commercial market through licensing on a non-exclusive,
25 royalty-free or reasonable royalty basis."

26 23. Thereafter, by an agreement dated October 12, 1987 ("the License Agreement"),
27 Columbia secured Genentech's agreement to pay royalties to Columbia. In exchange, Columbia
28 granted a non-exclusive license to certain patents and patent applications, including the '216 and

1 the '665 patents. That agreement required Genentech to pay more than one million dollars in up-
2 front fees not creditable against royalties, and required Genentech to pay substantial royalties to
3 Columbia based on particular defined sales. To date, Genentech has paid more than seventy
4 million dollars to Columbia under the License Agreement. According to Columbia, the
5 invention is its "single most successful innovation" and has been licensed to "23 companies
6 worldwide."

7 Columbia obtains the '017 patent

8 24. Notwithstanding having obtained the '216 patent and the '665 patent, both of
9 which Columbia effectively admitted claim the same invention, on June 18, 1991, Columbia
10 filed yet another application ("the '017 application"). That application also claimed priority to the
11 '513 application. Columbia represented to the PTO that the '017 application was a divisional of
12 application Serial No. 07/346,089.

13 25. In response, the PTO (1) rejected certain claims "as claiming the same invention"
14 as a certain claim in the '216 application, noting that "[t]his is a double patenting rejection," and
15 (2) noted that the claims presented "were not present in the parent application and were never
16 subjected to the requirement for restriction. Therefore, the present application is being examined
17 as a continuation of application Serial No. 07/346,089 and not as a divisional application."

18 26. The PTO also rejected certain other claims in the '017 application "under the
19 judicially created doctrine of obviousness-type double patenting as being unpatentable" over
20 certain claims of the '216 patent. The PTO noted that the conflicting claims were "not patentably
21 distinct from each other because the mammalian cells claimed in the instant application would
22 result from the processes claimed" in the '216 patent, and that the mammalian cells claimed were
23 "clearly obvious" over the '216 patent claims.

24 27. In response, Columbia did not contest that certain claims of the '017 application
25 claimed the same invention, or merely an obvious variant of the same invention, that was claimed
26 in the '216 patent. Instead, Columbia chose to submit a terminal disclaimer, by which Columbia
27 agreed that the term of the '017 patent would not extend beyond the August 16, 2000 expiration
28 date of the '216 patent. Subject to the terminal disclaimer, on January 12, 1993, the '017 patent

1 issued, with five claims, to Columbia as assignee of named inventors Richard Axel, Michael H.
2 Wigler, and Saul J. Silverstein. A true and correct copy of the '017 patent is attached hereto as
3 Exhibit 3.

4 28. The '017 patent issued with the notice that "[t]he portion of the term of this patent
5 subsequent to Aug. 16, 2000 [the '216's expiration date] has been disclaimed." Pursuant to the
6 terminal disclaimer, after August 16, 2000, the invention claimed in the '017 patent passed into
7 the public domain.

8 Columbia obtains the '275 patent – without entering a terminal disclaimer

9 29. As noted above, Columbia obtained an initial U.S. patent for its invention – the
10 '216 patent. Columbia thereafter sought to obtain additional U.S. patents for its invention.
11 Columbia was able to obtain those two additional patents only by disclaiming all of the rights to
12 the invention claimed in those patents after the '216 patent's expiration date. Despite that, on
13 June 7, 1995 – some *fifteen years* after filing the '513 application – Columbia filed *yet another*
14 U.S. application ("the '275 application") on its invention that again claimed priority to the '513
15 application. As initially presented, the '275 application contained 125 claims, which Columbia
16 thereafter amended several times due to, among other things, rejections based upon double
17 patenting.

18 30. In May 2002, after the '275 application had been pending for some seven years – a
19 delay caused by Columbia's dilatory responses to the PTO's Office Actions – a PTO Examiner
20 different from the Examiner who initially rejected the '275 application allowed certain pending
21 claims.

22 31. On September 24, 2002, the '275 patent issued. A true and correct copy is attached
23 hereto as Exhibit 4. As issued, the '275 patent contains 20 claims.

24 32. Columbia did not agree to a terminal disclaimer when it obtained the '275 patent,
25 unlike when it obtained the '665 and '017 patents.
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1 During the prosecution of the '275 patent, Columbia makes misrepresentations and
2 misleading omissions to the PTO that are material to the patentability of the '275 patent

3 33. On February 3, 1998, the Patent Examiner rejected all pending claims in the
4 application that matured into the '275 patent on the basis of double patenting over the claims of
5 the '017 patent regarding transformed Chinese Hamster Ovary ("CHO") cells.

6 34. On July 24, 1998, Columbia responded to the double patenting rejection by
7 canceling claim 132 and conceding the merits of the double patenting rejection for claims
8 regarding transformed CHO cells. Columbia then argued that by canceling claim 132 the
9 remaining claims became distinct from the transformed cells claimed in the '017 patent.

10 35. On September, 14, 1998, the Patent Examiner noted the cancellation of claim 132
11 and again rejected, though on different grounds, the remaining proposed claims of the
12 application.

13 36. On January 31, 2000 and on October 24, 2000, a new Patent Examiner rejected
14 the pending proposed claims, which did not claim transformed CHO cells, for double patenting
15 over the claims of the '216 patent.

16 37. On June 14, 2001, in response to the new Examiner's rejections, Columbia added
17 claims for transformed cells like those rejected by the previous Examiner. Indeed the same
18 prosecuting counsel who had responded to the February 3, 1998 Office Action in which the
19 Examiner rejected all the transformed cell claims for double patenting, resubmitted the
20 transformed cell claims without disclosing to the new Patent Examiner the prior rejection of
21 February 3, 1998 or the response of July 24, 1998. This omission was material and was intended
22 to deceive the PTO. Had this information been disclosed to the Examiner, Columbia could not
23 have obtained the '275 patent.

24 38. In addition to failing to inform the Examiner that the resubmitted claims had been
25 previously rejected, Columbia redrafted the rejected CHO claims to appear superficially different
26 while being virtually identical in substance. This misrepresentation was material and was
27 intended to deceive the PTO.

28

1 39. In addition to the above conduct, Columbia and/or others substantively involved
 2 in prosecution of the application leading to the '275 patent withheld material information from
 3 the PTO with the intent to deceive the PTO. The withheld information includes but is not limited
 4 to N. Mantei et al., "Rabbit β -globin mRNA Production in Mouse L-Cells Transformed with
 5 Cloned Rabbit β -globin DNA," *Nature* 281, pp. 40-46 (1979) ("Mantei Cotransformation
 6 Article"). Columbia, its named inventors, and/or its patent prosecution counsel knew of the
 7 Mantei Cotransformation Article, knew that the PTO would have considered the Mantei
 8 Cotransformation Article to be material, and intended to deceive the PTO about it. Indeed, the
 9 Mantei Cotransformation Article was cited during Columbia's prosecution of the earlier '216
 10 patent, which claims the same invention as the later '665, '017, and '275 patents. The article had
 11 also been cited in opposition to (1) a European patent application that Columbia had previously
 12 filed that also claimed priority to the '513 application; and (2) a Japanese patent application that
 13 Columbia had previously filed that also claimed priority to the '513 application.

14 40. In fact, Columbia purported to cite the Mantei Cotransformation Article in an
 15 Information Disclosure Statement submitted to the PTO during the '275 patent's prosecution. In
 16 response, the PTO refused to consider the citation to the Mantei Cotransformation Article
 17 because the citation was "not in conformance [with the PTO's Manual of Patent Examination and
 18 Procedures] and not considered." Despite this awareness of the article and awareness that the
 19 PTO would have considered it to be material, the article was not thereafter submitted in
 20 conformance with PTO rules for the PTO's consideration during the '275 patent's prosecution.
 21 The result is that the PTO did not consider the Mantei Cotransformation Article in assessing the
 22 validity of the '275 patent.

23 41. The withheld information also includes, but is not limited to K. Willecke et al.,
 24 "Cotransfer of Two Linked Human Genes into Cultured Mouse Cells," *Proc. Nat'l Acad. Sci.*
 25 *USA* 73(4), pp. 1274-1278 (1976) ("Willecke Cotransformation Article"). Columbia, its named
 26 inventors, and/or its patent prosecution counsel knew of the Willecke Cotransformation Article,
 27 knew that the PTO would have considered the Willecke Cotransformation Article to be material,
 28 and intended to deceive the PTO about it. Indeed, Columbia's named inventors cited the

1 Willecke Cotransformation Article prior to filing the first patent application in Wigler et al.,
2 "DNA-Mediated Transfer of Adenine Phosphoribosyltransferase Locus Into Mammalian Cells,"
3 Proc. Nat'l Acad. Sci. USA 76(3), pp. 1373-1376 (1976). In addition, the Examiner cited the
4 Willecke Cotransformation Article against the then-pending claims during the prosecution of the
5 earlier '665 patent, which claims the same invention as the '216, '017, and '275 patents. The
6 Examiner stated that "Willecke et al. teach the cotransfer of two linked genes into cultured mouse
7 cells using one gene coding for a selectable trait and producing proteins from each gene." Later
8 in the prosecution of the '665 patent and in maintaining the rejection of claims relating to linked
9 cotransformation, the Examiner stated that "Willecke et al. show linking two pieces of DNA for
10 cotransformation and one would expect similar behavior for other linked DNA."

11 42. Columbia purported to cite the Willecke Cotransformation Article in an
12 Information Disclosure Statement submitted to the PTO during the prosecution of the '275 patent.
13 In response, the PTO refused to consider the citation to the Willecke Cotransformation Article
14 because the citation was "not in conformance [with the PTO's Manual of Patent Examination and
15 Procedures] and not considered." Despite this awareness of the article and awareness that the
16 PTO would have considered it to be material, the Willecke Cotransformation Article was not
17 thereafter submitted in conformance with PTO rules for the PTO's consideration during the '275
18 patent's prosecution. The result is that the PTO did not consider the Willecke Cotransformation
19 Article in assessing the validity of the '275 patent.

20 43. The withheld information also includes but is not limited to Miller & Ruddle,
21 "Co-Transfer of Human X-Linked Markers into Murine Somatic Cells via Isolated Metaphase
22 Chromosomes," Proc. Nat'l Acad. Sci. USA 75(7), pp. 3346-3350 (1978) ("Miller
23 Cotransformation Article"). Columbia, its named inventors, and/or its patent prosecution counsel
24 knew of the Miller Cotransformation Article, knew that the PTO would have considered the
25 Miller Cotransformation Article to be material, and intended to deceive the PTO about it.
26 Indeed, the Miller Cotransformation Article was cited during Columbia's prosecution of the
27 earlier '665 patent, which claims the same invention as the '216, '017, and '275 patents.
28

1 44. Columbia purported to cite the Miller Cotransformation Article in an Information
 2 Disclosure Statement submitted to the PTO during the prosecution of the '275 patent. In
 3 response, the PTO refused to consider the citation to the Miller Cotransformation Article because
 4 the citation was "not in conformance [with the PTO's Manual of Patent Examination and
 5 Procedures] and not considered." Despite this awareness of the article and awareness that the
 6 PTO would have considered it to be material, the Miller Cotransformation Article was not
 7 thereafter submitted in conformance with PTO rules for the PTO's consideration during the '275
 8 patent's prosecution. The result is that the PTO did not consider the Miller Cotransformation
 9 Article in assessing the patentability of the '275 patent.

10 **Columbia materially breaches the License Agreement**

11 45. In a letter dated March 18, 2004, Columbia gave notice to Genentech that it was
 12 terminating the License Agreement due to the following alleged material breaches by Genentech:

13 (1) failing to pay all royalties due on Licensed Products manufactured on or after
 14 September 24, 2002, the date on which United States Patent No. 6,455,275 was
 15 issued; (2) failing to provide required reports for all such unpaid royalties; (3)
 16 failure to provide proper certified royalty reports; (4) failing to allow an audit of
 its books and records in accordance with the terms of the agreement; (5) failing to
 pay all fees due under the license agreement.

17 46. In a letter dated April 16, 2004, Genentech responded to Columbia's purported
 18 termination by explaining that the bases for Columbia's termination of the License Agreement
 19 were meritless and pretextual. Genentech stated that Columbia's pretextual termination of the
 20 License Agreement constituted a material breach of the agreement.

21 47. In its letter of April 16, 2004, Genentech also informed Columbia that because of
 22 Columbia's material breach Genentech would not make future royalty payments under the '275
 23 patent. Genentech is therefore not paying royalties to Columbia under the '275 patent.

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FIRST CLAIM FOR RELIEF

DECLARATORY JUDGMENT THAT THE

'275 PATENT IS INVALID BECAUSE OF DOUBLE PATENTING

48. Genentech hereby incorporates ¶¶ 1-47 of this complaint.

49. Columbia maintains that the '275 patent is valid and enforceable. Genentech maintains that all of the claims of the '275 patent are invalid and unenforceable because each of the inventions claimed in it is identical to, or is merely an obvious variant of, the inventions claimed in the '216, '665, and/or '017 patents. There is a case or controversy between the parties about whether the '275 patent is invalid and unenforceable because Columbia has asserted that the '275 patent is valid and enforceable, and that Genentech owes royalties under the '275 patent.

50. Accordingly, Genentech seeks this Court's declaratory judgment that the '275 patent is invalid because each of the claims in it is identical to, or is merely an obvious variant of, claims in the '216, '665, and/or '017 patents.

51. This is an exceptional case, and Genentech is entitled to an award of attorneys' fees pursuant to 35 U.S.C. § 285.

52. WHEREFORE, Genentech prays for relief as set forth below.

SECOND CLAIM FOR RELIEF

DECLARATORY JUDGMENT THAT THE '275 PATENT IS INVALID

AND UNENFORCEABLE BECAUSE OF PROSECUTION LACHES

53. Genentech hereby incorporates ¶¶ 1-52 of this complaint.

54. As set forth above, the patent claims of the '275 patent issued after unreasonable and unexplained delays in the prosecution of those claims. In light of those unreasonable and unexplained delays in the prosecution of the '275 patent, Genentech maintains that all of the claims of the '275 patent are invalid and unenforceable. Despite those unreasonable and unexplained delays, Columbia maintains that the '275 patent is valid and enforceable. There is a case or controversy between the parties about whether the '275 patent is invalid and unenforceable.

55. The delay has caused and will cause Genentech to suffer material prejudice.

1 56. Accordingly, Genentech seeks this Court's declaratory judgment that the '275
2 patent is invalid and unenforceable because of prosecution laches.

3 57. This is an exceptional case, and Genentech is entitled to an award of attorneys'
4 fees pursuant to 35 U.S.C. § 285.

5 58. WHEREFORE, Genentech prays for relief as set forth below.

6 **THIRD CLAIM FOR RELIEF**

7 **DECLARATORY JUDGMENT THAT THE '275 PATENT IS**
8 **UNENFORCEABLE BECAUSE OF INEQUITABLE CONDUCT**

9 59. Genentech hereby incorporates ¶¶ 1-58 of this complaint.

10 60. The '275 patent is unenforceable by reason of Columbia's inequitable conduct
11 during the prosecution of the '275 patent.

12 61. Columbia owed a duty of candor, good faith, and honesty to the PTO in the
13 prosecution of the '275 patent. Columbia breached this duty, with the requisite intent to deceive,
14 when before the '275 patent issued, Columbia and/or others substantively involved in prosecuting
15 the application leading to the '275 patent, were aware of information material to the patentability
16 of the claims of the '275 patent and withheld that information from the PTO.

17 62. The acts constituting Columbia's inequitable conduct include, but are not limited
18 to: (1) misleading the '275 patent examiner into withdrawing double-patenting rejections based
19 on the '017 patent; and (2) withholding material scientific references that had been cited during
20 the prosecution of the '216 and '665 patents.

21 63. Columbia's misrepresentations, misleading statements, omissions, and
22 manipulations were material and were made with the intent to deceive. Columbia thus
23 committed inequitable conduct while prosecuting the '275 patent, thereby making the '275 patent
24 unenforceable.

25 64. Accordingly, Genentech seeks this Court's declaratory judgment that the '275
26 patent is unenforceable because of inequitable conduct committed during its prosecution.

27 65. This is an exceptional case, and Genentech is entitled to an award of attorneys'
28 fees pursuant to 35 U.S.C. § 285.

66. WHEREFORE, Genentech prays for relief as set forth below.

FOURTH CLAIM FOR RELIEF

**DECLARATORY JUDGMENT THAT GENENTECH OWES
NO ROYALTIES UNDER THE '275 PATENT**

67. Genentech hereby incorporates ¶¶ 1-66 of this complaint.

68. Columbia contends that pursuant to the License Agreement between it and Genentech, Genentech must pay royalties to Columbia on the '275 patent. Genentech contends that the '275 patent is invalid and unenforceable and thus the License Agreement does not require Genentech to pay royalties to Columbia based on the '275 patent.

69. In particular, the License Agreement defines "Licensed Products" to mean "products, the manufacture, use or sale of which is covered by a claim of Licensed Patent Rights which have neither expired nor been held invalid by a court of competent jurisdiction from which no appeal has or may be taken." Because invalidity and unenforceability are distinct concepts under our patent laws, the License Agreement thereby does not require Genentech to pay royalties to Columbia if the Licensed Patents are unenforceable. The '275 patent is unenforceable.

70. Accordingly, Genentech is entitled to declaratory judgment that Genentech is entitled to recover any and all royalties based on the '275 patent paid by Genentech to Columbia under the License Agreement.

71. WHEREFORE, Genentech prays for relief as set forth below.

FIFTH CLAIM FOR RELIEF

BREACH OF CONTRACT

72. Genentech hereby incorporates ¶¶ 1-71 of this complaint.

73. Genentech has performed all conditions, covenants, and promises that it is required to perform under the License Agreement with Columbia.

74. On March 18, 2004, Columbia improperly terminated the License Agreement with Genentech on a pretextual basis.

1 75. Columbia's pretextual termination constitutes a material breach of its obligations
2 under the License Agreement.

3 76. As a proximate result of Columbia's breach, Genentech has suffered actual and
4 consequential damages.

5 WHEREFORE, Genentech prays for relief as follows:
6

7 **PRAYER FOR RELIEF**

8 1. The Court enter a declaratory judgment that the '275 patent is invalid because each
9 of its claims purports to claim the same invention, or an obvious variant thereof, as an invention
10 claimed in claims from the '216, '665, and/or '017 patents.

11 2. The Court enter a declaratory judgment that the '275 patent is invalid and
12 unenforceable because of prosecution laches.

13 3. The Court enter a declaratory judgment that the '275 patent is unenforceable
14 because of inequitable conduct committed during its prosecution.

15 4. The Court enter a declaratory judgment that the License Agreement does not
16 obligate Genentech to pay royalties under the '275 patent.

17 5. The Court award damages to Genentech resulting from Columbia's breach of its
18 License Agreement with Genentech.

19 6. The Court grant injunctive relief prohibiting Columbia from demanding any
20 further royalties under the License Agreement based on the '275 patent or on any pending
21 continuations, continuations-in-part, or divisional applications of the patents recited in those
22 agreements;

23 7. That Columbia be directed to pay Genentech's attorneys' fees incurred in
24 connection with this lawsuit pursuant to 35 U.S.C. § 285; and

25 8. That Genentech have such other and further relief as this Court may deem just and
26 proper.
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1 Dated: May 14, 2004

QUINN EMANUEL URQUHART
OLIVER & HEDGES LLP

2
3 By: Charles K. Verhoeven / PHS

4 John B. Quinn
5 Adrian M. Pruetz
6 Charles K. Verhoeven
7 Victoria F. Maroulis

8 Attorneys for Plaintiff
9 GENENTECH, INC.
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COMPLAINT

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1 CERTIFICATION OF INTERESTED ENTITIES OR PERSONS

2 Pursuant to Civil Local Rule 3-16, the undersigned certifies that the following listed
3 persons, associations of persons, firms, partnerships, corporations (including parent corporations)
4 or other entities (i) have a financial interest in the subject matter in controversy or in a party to
5 the proceeding, or (ii) have a nonfinancial interest in that subject matter or in a party that could
6 be substantially affected by the outcome of this proceeding:

7 Genentech, Inc.

8 Roche Holdings, Inc. owns approximately 60% of the issued common stock of Genentech
9 Inc., however, Genentech Inc., remains an independent, publicly traded company.

10
11
12 Dated: May 14, 2004

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